Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/037 Issued: 21 December 2018 at 14:00

Fabian +nCPAP evolution, Fabian Therapy evolution and Fabian HFO – Risk of total loss of patient ventilation.

Summary

Manufactured by Acutronic Medical Systems AG – Ventilator may switch off without user input, deliver incorrect ventilation or may fail to alarm.

Action

- Identify all affected ventilators – see the Problem section of this alert or the manufacturer's Field Safety Notices (FSNs) reference FSCA 18-003 and FSCA 18-004.
- Use an alternative ventilator for treatment if available.
- If no alternative is available, carry out – and document – a risk assessment based on a clinical risk-benefit analysis before using the ventilator.
- If you continue to use an affected ventilator, make sure you follow the instructions in the manufacturer's FSNs and be extra vigilant.
- Disconnect any ethernet connections from the device.
- All affected ventilators that have unexpectedly shut down or had power cycling should be removed from service.
- Complete the End User Response form(s) and return to Kevin.Nash@inspiration-healthcare.com. If you are affected by both FSNs, you must return both forms.
- Report any incidents or complaints involving this product to info@acutronic-medical.ch

Action by
All healthcare professionals who are responsible for or who use these devices.

Deadlines for actions
Actions underway: 04 January 2019
Actions complete: 15 February 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem

This alert covers two sets of problems affecting multiple devices.

1. FSCA 18-003

This FSCA affects the following devices:

Product	Serial number (SN)
fabian +nCPAP evolution	AN-01803 to AN-03013
fabian Therapy evolution	AT-01572 to AT-03025

Description	Part number	Delivery timeframe to distributors
fabian Therapy evolution front housing	121212	1st of January 2017 – 1st of June 2018
fabian +nCPAP evolution front housing	122212	

There is a possibility that the front panel of certain Fabian +nCPAP evolution and Fabian Therapy evolution ventilators could short circuit and shut down without warning. The ventilator will not restart. To continue the treatment, a new ventilator must be used.

The UK distributor, Inspiration Healthcare, will inspect ventilators in the range above to identify whether the front panel is affected and if so, replace it.

Until the front panel has been replaced, follow the advice in the manufacturer's FSN and the Action section of this alert.

2. FSCA 18-004

This FSCA affects the following devices:

Product	Serial number (SN) prefix
fabian HFO	AH / AK / AI / AL / 20
fabian +nCPAP evolution	AN
fabian Therapy evolution	AT

There are multiple problems with certain Fabian +nCPAP evolution, Fabian Therapy evolution and Fabian HFO ventilators.

Software defects have been identified that could cause sudden loss of mechanical ventilation and/or loss of positive pressure.

Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Risk of harm to patient if FI Card is not followed
A Graphical User Interface (GUI) freeze/crash could occur when the device is connected to an Ethernet network. It could also cause loss of ventilation with alarming during patient use.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia
When saving, loading or manipulating trends a system failure or application error could occur causing loss of ventilation with alarming.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia

Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Risk of harm to patient if FI Card is not followed
Switching between languages could result in a GUI freeze/crash causing loss of ventilation with alarming.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia
In SIMV breath delivery while using volume limit mode, the ventilator may deliver incorrect ventilation skipping expected mandatory breaths.	Affected	Affected	Not affected	transient, moderate hypoxemia / hypercapnia
Pressure might not be immediately released when high peak inspiratory pressure (PIP) alarm is triggered (when high PIP alarms are set less than 12 mbar above the set PIP) as pressure release is not tied to it. Pressure relief occurs 12 mbar above the set PIP and pressure is released till ZEEP.	Affected	Affected	Affected	moderate hypotension, barotrauma
User bypass of the flow sensor and O2 sensor calibration could result in incorrect ventilation.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia.
In dual limb CPAP ventilation, the ventilator may deliver a lower number of burst breaths than what is set.	Affected	Affected	Not affected	transient, moderate hypoxemia / hypercapnia.

Further software defects have been identified that could result in delayed awareness by caregivers of a potentially hazardous event.

Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Risk of harm to patient if FI Card is not followed
In case of an error in our device's alarm system, there may be either a visual alarm without audible indication, or a visual and audible technical alarm without an associated alarm message.	Affected	Affected	Affected	severe hypoxemia / hypercapnia, possible death
While using volume guarantee option, it is possible that alarm thresholds may be set such that disconnection of the patient circuit does not generate an alarm.	Affected	Affected	Not affected	severe hypoxemia / hypercapnia, possible death

Acutronic are developing a software update to resolve these issues and plan to make it available by April 2019. When it becomes available, Inspiration Healthcare will install it on affected devices.

Until the updated software becomes available, follow the guidance provided in the FI card sent with the manufacturer's FSN and the advice in the Action section of this alert.

Manufacturer contacts

Acutronic
Tel: +41 44 729 70 80
Email: info@acutronic-medical.ch

UK Distributor contacts

Inspiration Healthcare
Kevin Nash, Quality and Compliance Engineer
Tel: 0127 352 6504
Kevin.Nash@inspiration-healthcare.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- EBME departments
- Equipment stores
- Equipment libraries and stores
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Maternity units
- Medical directors
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Operating department practitioners
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Paediatrics departments

- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector with a neonatal intensive care department

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/037** or 2018/011/029/701/023 and 2018/012/010/291/006.

Technical aspects
Ben Satchell and Emma Rooke, MHRA

Tel: 0203 080 6488 and 0203 080 6609

Email: benjamin.satchell@mhra.gov.uk and emma.rooke@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).